REMARKS

1. STATUS OF THE CLAIMS

Claims 1-35 were originally filed in the application. Claims 1-13 and 21-22 were elected in a Response to Restriction Requirement mailed September 27, 2002. Claims 3, 6-8, and 12 were amended in a Response to Office Action mailed June 13, 2003. Claims 3, 6, and 12 are amended herein. Support for the present amendments can be found at page 7, lines 21-32 and page 54, lines 8-28 of the specification and in Figure 4. Claims 1-2, 5-6, 9-11, 13-20, and 23-35 were canceled. Claims 3, 6-8, 12, and 21-22 are currently pending in this application.

2. REJECTION OF CLAIMS 3, 6-8, and 21-22 UNDER THE JUDICIALLY CREATED DOCTRINE OF OBVIOUSNESS-TYPE DOUBLE PATENTING OVER CLAIMS 1-5 AND 8-15 OF U.S. PATENT NO. 5,753,504

Claims 3, 6-8, and 21-22 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-5 and 8-15 of U.S. Patent No. 5,753,504. The present rejection is moot in view of the terminal disclaimer of claims 3, 6-8, and 21-22 filed herewith under 37 C.F.R. § 1.321.

3. REJECTION OF CLAIMS 3,6-8, 12, AND 21-22 UNDER 35 U.S.C. 102(b)

The Examiner alleges that claims 3, 6-8, 12, and 21-22 are anticipated under 35 U.S.C. § 102(b) by Leturcq et al (Journal of Cellular Biochemistry (1992) Supplement 16, Part C, Page 151, Abstract CB109). The present rejection is respectfully traversed.

A. Response to the Rejection of Claim 3

Claim 3, as amended, recites a monoclonal antibody that has a

binding specificity to LBP, to denatured LBP, and to a complex containing LBP and LPS, wherein the binding specificity is that of Mab 4D7, Mab 5C5, Mab 6B6, Mab 8C9, Mab 18G4, or Mab 24B7. Leturcq et al., does not teach these claim elements. Therefore, Leturcq et al., cannot anticipate claim 3.

The Examiner asserts that Leturcq et al. teaches monoclonal antibody Mab 8C9 (see page 4 of the Office Action mailed August 26, 2003). To the contrary, Leturcq et al. at best mentions the existence of a monoclonal antibody labeled 8C9. However, Leturcq et al. does not disclose binding specificities of 8C9 to LBP, and to a complex containing LBP and LPS such that one skilled in the art is able to make and use a monoclonal antibody having each of the claimed binding specificities. Furthermore, contrary to the teaching of Leturcq et al., Mab 8C9 of the present invention immunoreacts with native LBP (see Figure 4 of the specification). Leturcq et al. states that 8C9 "recognizes denatured LBP only". Thus, the claimed monoclonal antibody having the binding specificities of Mab 8C9 as defined in specification is different from the antibody labeled 8C9 in Leturcq et al. Therefore, Leturcq et al. cannot anticipate the claimed monoclonal antibody because Leturcq et al. is not an enabling disclosure and because Leturcq et al. does not teach all of the elements of the claimed invention.

The Examiner also asserts that Leturcq et al. teaches monoclonal antibody 18G4 (see page 4 of the Office Action). However, Leturcq et al. does not disclose the claimed binding specificity of 18G4 to denatured LBP such that one skilled in the art is able to make and use a monoclonal antibody having each of the claimed binding specificities. Therefore, Leturcq et al. cannot anticipate the claimed monoclonal antibody because Leturcq et al. is not an enabling disclosure and because Leturcq et al.

does not teach all of the elements of the claimed invention.

The Examiner further asserts that the monoclonal antibodies 1E8, 2B5, and 18G4 are taught by Leturcq et al., by arguing that these antibodies have the same structure and functional abilities as those recited by claim 3, and, therefore, 1E8, 2B5, and 18G4 allegedly anticipate claim 3 (see page 5 of the Office Action). This assertion is respectfully traversed.

Regarding Mab 1E8, claim 3 does not recite monoclonal antibody Mab 1E8. In addition, Leturcq et al. does not provide guidance on the binding specificities of Mab 1E8 to denatured LBP. One skilled in the art cannot use the disclosure of the monoclonal antibody labeled 1E8 to make and use a monoclonal antibody having the claimed binding specificities of Mab 4D7, Mab 5C5, Mab 6B6, Mab 8C9, Mab 18G4, or Mab 24B7. Therefore, Mab 1E8 cannot anticipate claim 3 because claim 3 does not recite Mab 1E8 and because the claimed binding specificities of Mab 1E8 are not enabled in Leturcq et al.

Regarding Mab 2B5, Leturcq et al. does not disclose a monoclonal antibody labeled 2B5, therefore, 2B5 cannot anticipate claim 3.

Regarding Mab 18G4, and as discussed above, Leturcq et al. does not provide an enabling disclosure of the claimed binding specificity of Mab 18G4 to denatured LBP. Thus, Leturcq et al. cannot anticipate the monoclonal antibody or Mab 18G4 recited in claim 3 because Leturcq et al. is not an enabling disclosure.

The Examiner still further asserts that, "because the Patent Office does not have the facilities for examining and comparing applicant's peptide with the peptide of the prior art reference, the burden is upon the applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed monoclonal antibody of [sic] the

prior art". The present assertion is respectfully traversed.

The present assertion is irrelevant because anticipation can only be established when each and every element of the claimed invention is disclosed in the prior art and wherein each disclosed element is enabled in the prior art reference. The binding specificity of Mab 4D7, Mab 5C5, Mab 6B6, Mab 8C9, Mab 18G4, or Mab 24B7 to each of LBP, to denatured LBP, and to a complex containing LBP and LPS is not disclosed or enabled in Leturcq et al. Thus, Leturcq et al. does not anticipate claim 3 because each and every element of the claimed invention is not disclosed in Leturcq et al. and because monoclonal antibodies 1E8, 2B5, and 18G4 are not enabled in Leturcq et al. There can be no burden on the applicant to compare the claimed monoclonal antibody to a prior art monoclonal antibody without a teaching of each and every element of the claimed invention wherein each element is enabled in the prior art.

B. Response to the Rejection of Claims 6-8

The Examiner asserts that monoclonal antibodies 1E8, 2B5, and 18G4 are taught by Leturcq et al. and that they are the same antibodies which the instant application teaches as being able to inhibit the binding of LPS to CD14 (see the first full paragraph on page 5 of the Final Office Action). As discussed above in regard to the response to the rejection of claim 3, 2B5 is not disclosed in Leturcq et al., 1E8 is not recited in the claimed invention, and Leturcq et al. does not enable one skilled in the art to make or use 1E8, 2B5, or 18G4 as claimed. Accordingly, Leturcq et al. cannot anticipate claims 6-8 because Leturcq et al. does not teach all elements of the claimed invention.

Furthermore, claims 6-8 recite, or depend from a claim that

recites, a monoclonal antibody that inhibits LBP-mediated binding of LPS to CD14. Leturcq et al. does not teach a monoclonal antibody that inhibits LBP-mediated binding of LPS to CD14. Therefore, again, Leturcq et al., cannot anticipate claims 6-8 because Leturcq et al. does not teach all elements of the claimed invention.

C. Response to the Rejection of Claim 12

Claim 12 recites a hybridoma cell line that produces a monoclonal antibody that inhibits LBP-mediated binding of LPS to CD14. Leturcq et al. does not teach a monoclonal antibody that inhibits LBP-mediated binding of LPS to CD14. Therefore, Leturcq et al., cannot anticipate claim 12 because Leturcq et al. does not teach all elements of the claimed invention.

D. Response to the Rejection of Claims 21 and 22

The present rejection of claims 21 and 22 under 35 U.S.C. § 102(b) is a new rejection in the Final Office Action mailed August 26, 2003. The Examiner failed to state a basis for the present rejection in the Final Office Action. Furthermore, claims 21 and 22 are compositions and no element in Leturcq et al. was identified against claims 21 and 22 by the Examiner. Accordingly, the present rejection should be withdrawn because no *prima facie* basis for a rejection of claims 21 and 22 under 35 U.S.C. § 102(b) is provided on the record.

4. REJECTION OF CLAIMS 3,6, and 12 UNDER 35 U.S.C. § 112, SECOND PARAGRAPH

The Examiner rejected claims 3, 6, and 12 under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The present rejection is respectfully traversed. However, in view of the

amendments to the claims, it is believed that the present rejection is moot.

CONCLUSION

The Applicant respectfully requests that the Examiner enter the response herein, withdraw all claim rejections, and place the claims in condition for allowance.

The Examiner is requested to contact the representative for the Applicants, to discuss any questions or for clarification. If there are any further fees associated with this response, the Director is authorized to charge our Deposit Account No. 19-0962.

Respectfully submitted,

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Date

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